



PATENT

"Express Mail" label number RB765493674

Date of Deposit MAY 18, 1992

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

Date 5/18/92 By R.D. [Signature]  
Commissioner of Patents and Trademarks  
Washington, D.C. 20231

Sir:

This is a request under 37 CFR 1.62 for filing a File Wrapper

- ☒ Continuation  
☐ Division  
☐ Continuation-in-part

of Application Serial No. 528,593, filed May 24, 1990, of Gary Van Nest, et al. for ADJUVANT FORMULATION COMPRISING A SUBMICRON OIL DROPLET EMULSION

☐ A Verified Statement to Establish Small-Entity Status under 37 CFR 1.19 and 37 CFR 1.27

- ☐ is enclosed  
☐ was filed in the above-identified parent application.

☐ Please record the enclosed Assignment.

☒ Please amend the Specification by inserting before the first line:

-- CROSS REFERENCE TO RELATED APPLICATIONS

~~This application is a Continuation of U.S. Application Serial No. 07/528,593, filed May 24, 1990, which is Continuation-In-Part of U.S. Application Serial No. 357,035, filed May 25, 1989.~~

☒ Applicant petitions for a 3-month extension of time to respond in Application Serial No. 07/528,593. A Petition for Extension of Time is enclosed.

☐ Also enclosed are:

20464832  
051592

2.85

CHIR-001/02US

#13  
Pres. Gmth. D.  
w/ exhibits  
6-18-92

EO 72  
6-18-92

- ☐ An Information Disclosure Statement
- ☐ A Petition for Expedited Foreign Filing License
- ☐ A Declaration of Availability under MPEP 608.01(p)C.
- ☐ An Associate Power of Attorney
- ☐ \_\_\_\_\_.

☒ Please enter the Amendment/Response under Sec. 1.116 filed and unentered in Application Serial No. \_\_.

☒ A request for a telephonic interview is enclosed.

☒ Please cancel Claim(s) 10-28 and 31-35.

Fees for this Request are calculated as set forth below:

CLAIMS AFTER ENTRY OF ANY AMENDMENTS, LESS ANY CANCELLED CLAIMS

FOR:	(Col. 1)	(Col. 2)*	SMALL ENTITY		OTHER THAN A	
	NO. FILED	NO. EXTRA	RATE	FEE	SMALL ENTITY	RATE FEE
Basic Fee				\$345		\$690
Total Claims	11 -20=	15	x10=	\$	x 20=	\$
Indep Claims	2 - 3=	0	x36=	\$	x 72=	\$
<input type="checkbox"/> Multiple Dependent Claims Presented		+110=		\$	+220=	\$
Total Filing Fee:				\$		\$690.00

\* If the difference in Col. 1 is less than zero, enter "0" in Col. 2

<u>Extension of Time:</u>	<u>Small Entity</u>	<u>Large Entity</u>
<input type="checkbox"/> One Month.....	\$ 55.00	
<input type="checkbox"/> One Month.....		\$110.00
<input type="checkbox"/> Two Months.....	\$175.00	
<input type="checkbox"/> Two Months.....		\$350.00
<input type="checkbox"/> Three Months.....	\$405.00	
<input checked="" type="checkbox"/> Three Month.....		\$810.00
<input type="checkbox"/> Four Months.....	\$640.00	
<input type="checkbox"/> Four Months.....		\$1,280.00

20464832  
051892

2.  
86

Extension of Time Fee:

\$ 810.00

☐ Assignment Recording Fee

\_\_\_ Assignments @ \$40.00 each

\$\_\_\_

☐ Petition for Expedited Foreign  
Filing License.....\$130.00

\$\_\_\_

Other fees (list individually)

(none)

Total Other Fees:

\$ 0

TOTAL FEES: \$ 1,500.00

☒ A check including the amount of the above indicated TOTAL FEES is attached.

☐ Please charge Deposit Account No. 03-3117 in the amount of \$ .

☐ A check in the amount of \$\_\_\_ is attached.

☐ No fee is required.

☒ Conditional Petition for Extension of Time: An extension of time is requested in the present and/or the above-referenced parent application to provide for timely filing if an extension of time is still required after all papers filed with this transmittal have been considered.

☒ The Commissioner is hereby authorized to charge any underpayment of the following fees associated with this communication, including any necessary fees for extension of time, or credit any overpayment to Deposit Account No. 03-3117:

☒ Any filing fees under 37 CFR 1.16 including fees for the presentation of extra claims.

☒ Any patent application processing fees under 37 CFR 1.17.

20464832  
051892

3/  
87

A duplicate copy of this sheet is attached for accounting purposes.

Respectfully submitted,

COOLEY GODWARD CASTRO  
HUDDLESON & TATUM

Date: 5/18/92

By: *Richard L. Neeley*

Richard L. Neeley, Ph.D.  
Reg. No. 30,092

Cooley Godward Castro  
Huddleson & Tatum  
5 Palo Alto Square  
4th Floor  
Palo Alto, CA 94306  
(415) 494-7622

PATENT



07/835905

CHIR-001/02US

#14  
Letter re:  
Reg. Interview  
ur 6/18/92

"Express Mail" label number RB765493674

Date of Deposit MAY 18, 1992

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

Date

5/18/92

By

R. D. [Signature]

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Gary Van Nest, et al.

Serial No. Not yet assigned

Filed: Herewith

For: ADJUVANT FORMULATION  
COMPRISING A SUBMICRON  
OIL DROPLET EMULSION

)  
) Examiner: Kraus, E.  
) (in parent case)

)  
) Art Unit: 1811  
) (in parent case)

)  
) REQUEST FOR TELEPHONIC  
) INTERVIEW PRIOR TO INITIAL  
) EXAMINATION

)  
) Palo Alto, CA 94306

Commissioner of Patents and Trademarks  
Washington, D.C. 20231

Sir:

Prior to examination, Applicant requests that the new Examiner assigned to this case telephone its undersigned representative in order to discuss a declaration to be presented demonstrating certain properties of compositions of the invention.

Applicant has been informed that the Examiner previously in charge of this application is no longer associated with this case and that a new Examiner will be assigned upon the filing of this file wrapper continuation. Prosecution of this application can be significantly advanced if the newly assigned Examiner will call Applicant's undersigned representative in order to discuss the proposed declaration.

20465317  
051892

The advisory action in the parent application indicated that the particular diameter limitation on the size of the metabolizable oil droplets in an emulsion of the invention required additional consideration by the Examiner. Applicant has available new data further demonstrating the particular efficiency of compositions of the invention in large mammals, in direct contrast to testing in small animals such as guinea pigs which teaches that no advantage would be expected with compositions of the invention. Applicant's representative would like to discuss this information with the Examiner prior to presenting a declaration in order that the data be of a type considered desirable by the Examiner and also be presented in sufficient detail.

Several types of data are available, as indicated by the enclosed exhibits which summarize the data. Exhibit 1 is a series of graphs showing antibody titer in chimpanzees inoculated with an antigen (ENV 2-3) and any of several adjuvants that differ primarily in particle size (MF 59 is a composition of the invention; the remaining compositions have larger droplet sizes). Exhibit 2 is a similar demonstration of the antibody titer in baboons of a composition containing an adjuvant of the invention (MF 59) and various other adjuvants.

Exhibits 3-5 show an interesting aspect of the present invention, as these figures summarize data obtained with identical antigens and adjuvant formulations in different species of animals. Compositions of the invention can be seen to be particularly effective in large animals, such as baboons and goats, a property that would not be expected from the results obtained in small animals such as rabbits and guinea pigs.

Applicant would particularly like to discuss with the newly assigned Examiner the form in which the data represented

by these summary charts should be presented. In the past, Applicant's representative has noted that different Examiners wish to receive the data in different degrees of detail. In order to ensure that the data is presented properly the first time and therefore does not require multiple considerations by the Examiner, Applicant specifically requests a telephonic interview prior to examination of this application in order that the data can be presented in the desired form. The declaration presenting the data will then be promptly filed for consideration by the Examiner.

Respectfully submitted,

COOLEY GODWARD CASTRO  
HUDDLESON & TATUM

Date: 5/18/92

By: Richard L. Neeley  
Richard L. Neeley, Ph.D.  
Reg. No. 30,092

Cooley Godward Castro  
Huddleson & Tatum  
5 Palo Alto Square  
4th Floor  
Palo Alto, CA 94306  
(415) 494-7622

20465317

20465317  
051892